

EC Declaration of Conformity

The Company:

Andreas Fahl Medizintechnik-Vertrieb GmbH
August-Horch-Straße 4a
51149 Köln, Germany
SRN: DE-MF-000006665

hereby account for the medical devices listed in the annex on which this declaration is based, that they conform to the following EC directive:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)

Product group	LARYVOX® Uniek
Basic UDI-DI	4051948X25010LRVXUNIKVALR
Class acc. to Directive 93/42/EEC	Class IIb
Classification Rule	8
REFs / Medical Devices	see annex on next page
Intended purpose	The LARYVOX® UNIEK is a long-term voice prosthesis made of medical silicone for voice rehabilitation after a laryngectomy. The LARYVOX® UNIEK is intended for long-term application. The voice prosthesis prevents closure of the tracheo-oesophageal shunt canal. It enables air to flow into the pharynx and thus allows speech. The voice prosthesis seals the tracheoesophageal shunt canal during swallowing.
Conformity assessment procedure	Medical devices listed in the annex conform to "essential requirements" of this directive as per Annex I. Conformity of the medical devices to Directive 93/42/EEC is declared as per Annex II. The manufacturer assumes sole responsibility for compliance with the requirements of Directive 93/42/EEC and all other Union legislation applicable to the medical devices listed in the annex below.

The manufacturer is subject to supervision by the notified body:
DNV MEDCERT GmbH (CE 0482), Pilatuspool 2, 20355 Hamburg, Germany

In accordance with Article 120 of the Medical Device Regulation (EU) 2017/745 (MDR), last amended by Regulation (EU) 2023/607, and MDCG 2020-3 Rev.1, the change of the covered products is considered a non-significant change.

This Declaration of Conformity applies to all devices supplied after the production date until further notice. In the event of changes for the conformity assessment procedure, device alterations and changes to normative or regulatory requirements, conformity will be re-evaluated and declared again.

Cologne, 23.04.2025

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Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
X25010-05	LARYVOX® Uniek U.L.R. 21Fr., Size 5mm
X25010-06	LARYVOX® Uniek U.L.R. 21Fr., Size 6mm
X25010-07	LARYVOX® Uniek U.L.R. 21Fr., Size 7mm
X25010-08	LARYVOX® Uniek U.L.R. 21Fr., Size 8mm
X25010-09	LARYVOX® Uniek U.L.R. 21Fr., Size 9mm
X25010-10	LARYVOX® Uniek U.L.R. 21Fr., Size 10mm
X25010-11	LARYVOX® Uniek U.L.R. 21Fr., Size 11mm
X25010-13	LARYVOX® Uniek U.L.R. 21Fr., Size 13mm
X25020-05	LARYVOX® Uniek U.L.R. 24Fr., Size 5mm
X25020-06	LARYVOX® Uniek U.L.R. 24Fr., Size 6mm
X25020-07	LARYVOX® Uniek U.L.R. 24Fr., Size 7mm
X25020-08	LARYVOX® Uniek U.L.R. 24Fr., Size 8mm
X25020-09	LARYVOX® Uniek U.L.R. 24Fr., Size 9mm
X25020-10	LARYVOX® Uniek U.L.R. 24Fr., Size 10mm
X25020-11	LARYVOX® Uniek U.L.R. 24Fr., Size 11mm
X25020-13	LARYVOX® Uniek U.L.R. 24Fr., Size 13mm
X25030-045	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 4,5mm
X25030-05	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 5mm
X25030-06	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 6mm
X25030-07	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 7mm
X25030-08	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 8mm
X25030-09	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 9mm
X25030-10	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 10mm
X25030-11	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 11mm
X25030-125	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 12,5mm
X25030-13	LARYVOX® Uniek 2 U.L.R. 22,5Fr., Size 13mm